Establishment Registration

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October 22, 2019

Learning Objectives

- Know the Who, When, What & How of Establishment Registration
- Know the Types of Establishment Registration SPLs
- Be able to discuss How to Avoid the Most Common Errors

Who Must Register?

- With certain exemptions, any establishment engaged in the manufacture, repacking, relabeling, or salvaging of a drug product for commercial distribution in the U.S. is required to register with FDA.

- Most exemptions are listed on the eDRLS website.

When to Register?

- §207.21 When must initial registration information be provided?

- (a) Registrants must register each domestic establishment no later than 5 calendar days after beginning to manufacture, repack, relabel, or salvage a drug or an animal feed bearing or containing a new animal drug at such establishment.

- (b) Registrants must register each foreign establishment before a drug or an animal feed bearing or containing a new animal drug manufactured, repacked, relabeled, or salvaged at the establishment is imported or offered for import into the United States.

When to Update Your Establishment Registration

- Annual registration renewal to be submitted between Oct. 1 and Dec. 31
- Expedited updates to be provided within 30 days of a change
  - Closing or selling an establishment
  - Changing an establishment's name or physical address
  - Changing the name, mailing address, telephone number, or email address of the official contact or the United States agent.

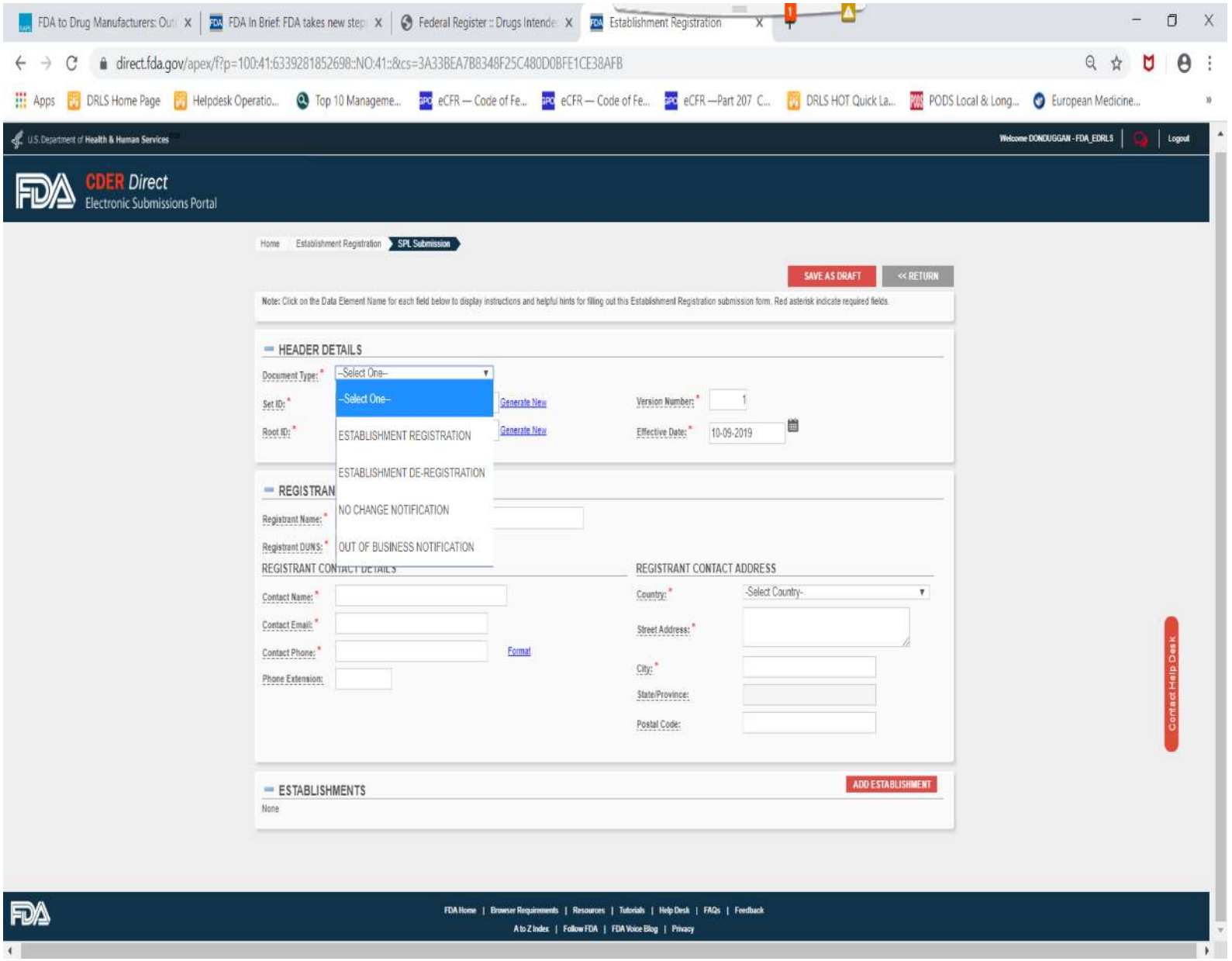
Notes about Registration

- Registration SPL's received from October 1st through – December 31st are good until the end of the following year. Those received from January 1st through September 30th are good to the end of the year they are received.
- Since Private Label Distributors do not manufacture, they should not register.
- Registration data is used for inspections and imports
- A Product Listing SPL will fail validation if the Establishment is not registered

More Notes about Registration

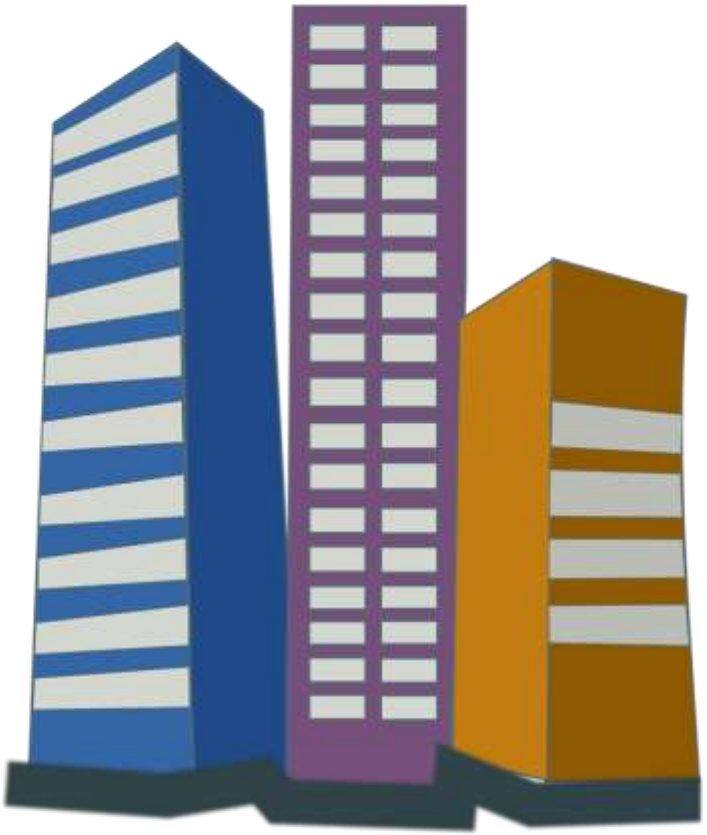
- There are no FDA fees for Establishment Registration
- If you have never registered before you will not have an FEI number. You will be assigned one in 60 days or less from ORA.

Establishment Registration SPL Types

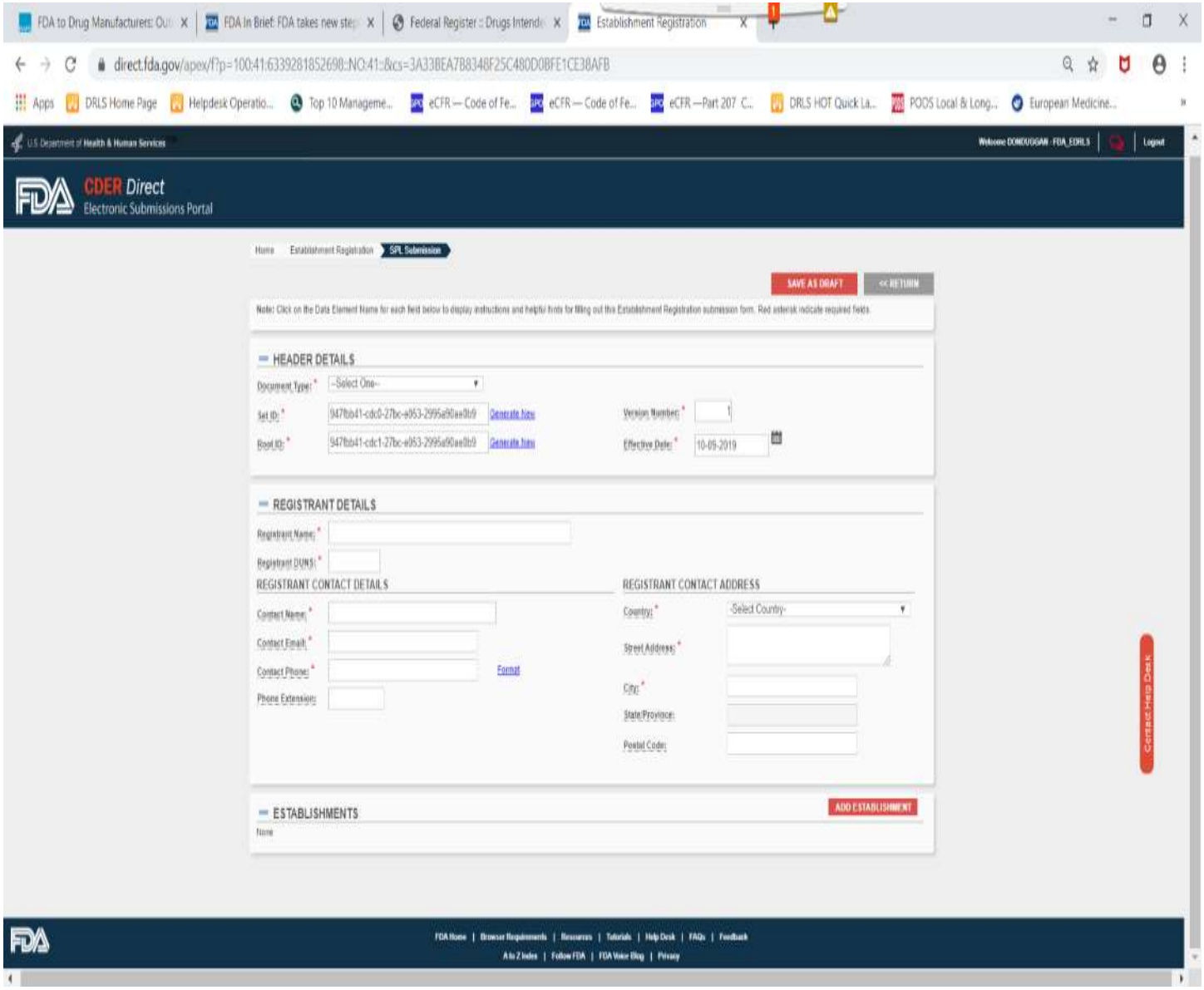


Establishment Registration SPL

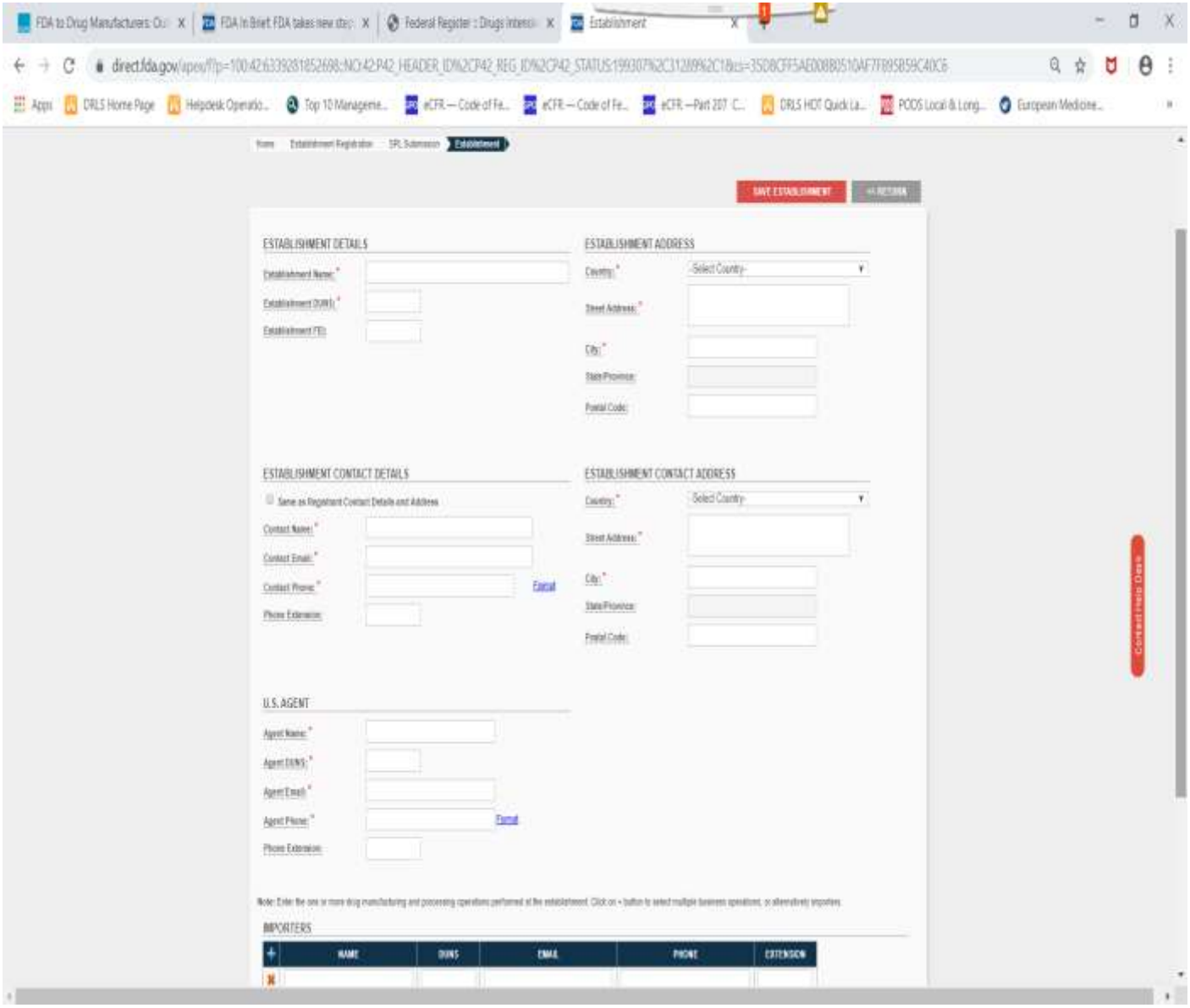
- New Establishment Registration or an update to an existing Establishment Registration



Main Form


FDA to Drug Manufacturers: Out
FDA In Brief: FDA takes new step
Federal Register :: Drugs Intende
Establishment Registration
direct.fda.gov/apex/f?p=100:41:6339281852698::NO:41::&cs=3A33BEA7B8348F25C480D0BFE1CE38AFB
Apps
DRLS Home Page
Helpdesk Operatio...
Top 10 Manageme...
eCFR — Code of Fe...
eCFR — Code of Fe...
eCFR — Part 207 C...
DRLS HOT Quick La...
PODS Local & Long...
European Medicine...
U.S. Department of Health & Human Services
Logout
CDER Direct
Electronic Submissions Portal
Home
Establishment Registration
SPL Submission
SAVE AS DRAFT
<< RETURN
Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filing out this Establishment Registration submission form. Red asterisk indicate required fields.
HEADER DETAILS
Document Type: *
-Select One-
Set ID: *
947fbb41-cdc0-27bc-e053-2995a90ae0b9
Generate New
Root ID: *
947fbb41-cdc1-27bc-e053-2995a90ae0b9
Generate New
Version Number: *
1
Effective Date: *
10-09-2019
REGISTRANT DETAILS
Registrant Name: *
Registrant DUNS: *
REGISTRANT CONTACT DETAILS
Contact Name: *
Contact Email: *
Contact Phone: *
Format
Phone Extension:
REGISTRANT CONTACT ADDRESS
Country: *
-Select Country-
Street Address: *
City: *
State/Province:
Postal Code:
ESTABLISHMENTS
ADD ESTABLISHMENT
None
Contact Help Desk
FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Feedback
A to Z Index | Follow FDA | FDA Voice Blog | Privacy

Adding an Establishment

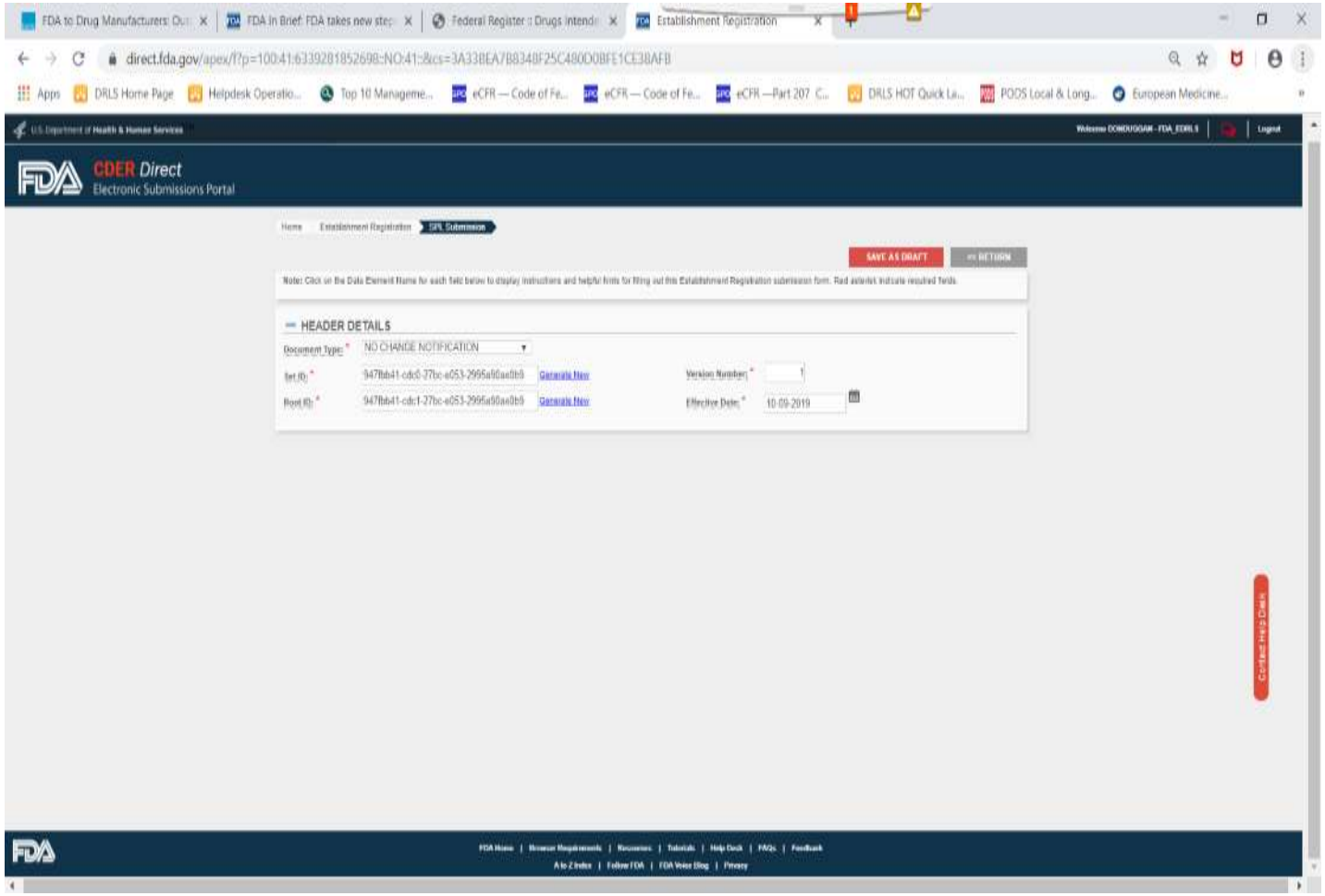


NO Change Notification SPL

- Easily re-register providing there are no updates required to the previously submitted Establishment Registration

From 10/1-12/31 ONLY!

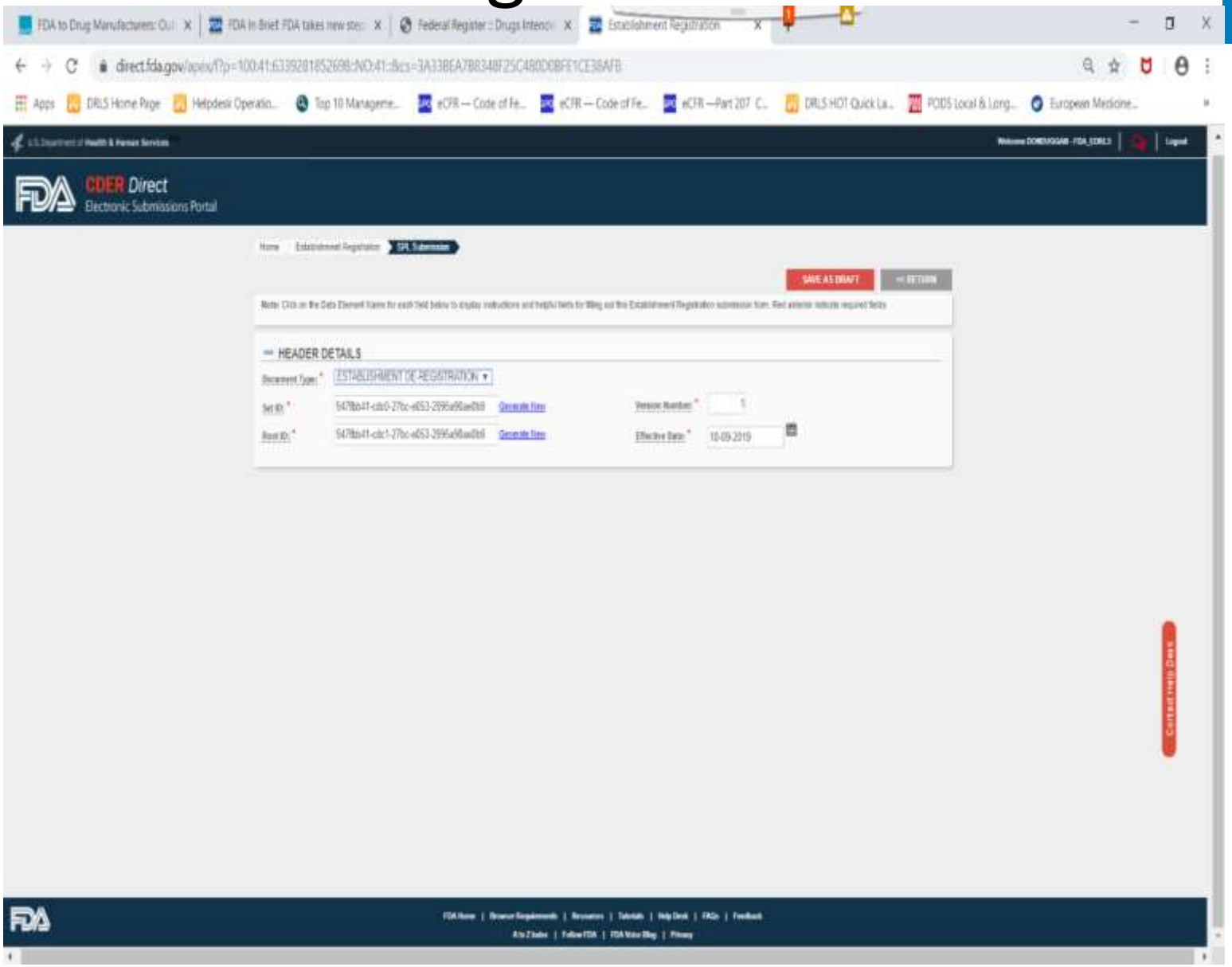
No Change Notification



De-Registration SPL

- De-register because the firm is no longer manufacturing drug products for commercial distribution in the US

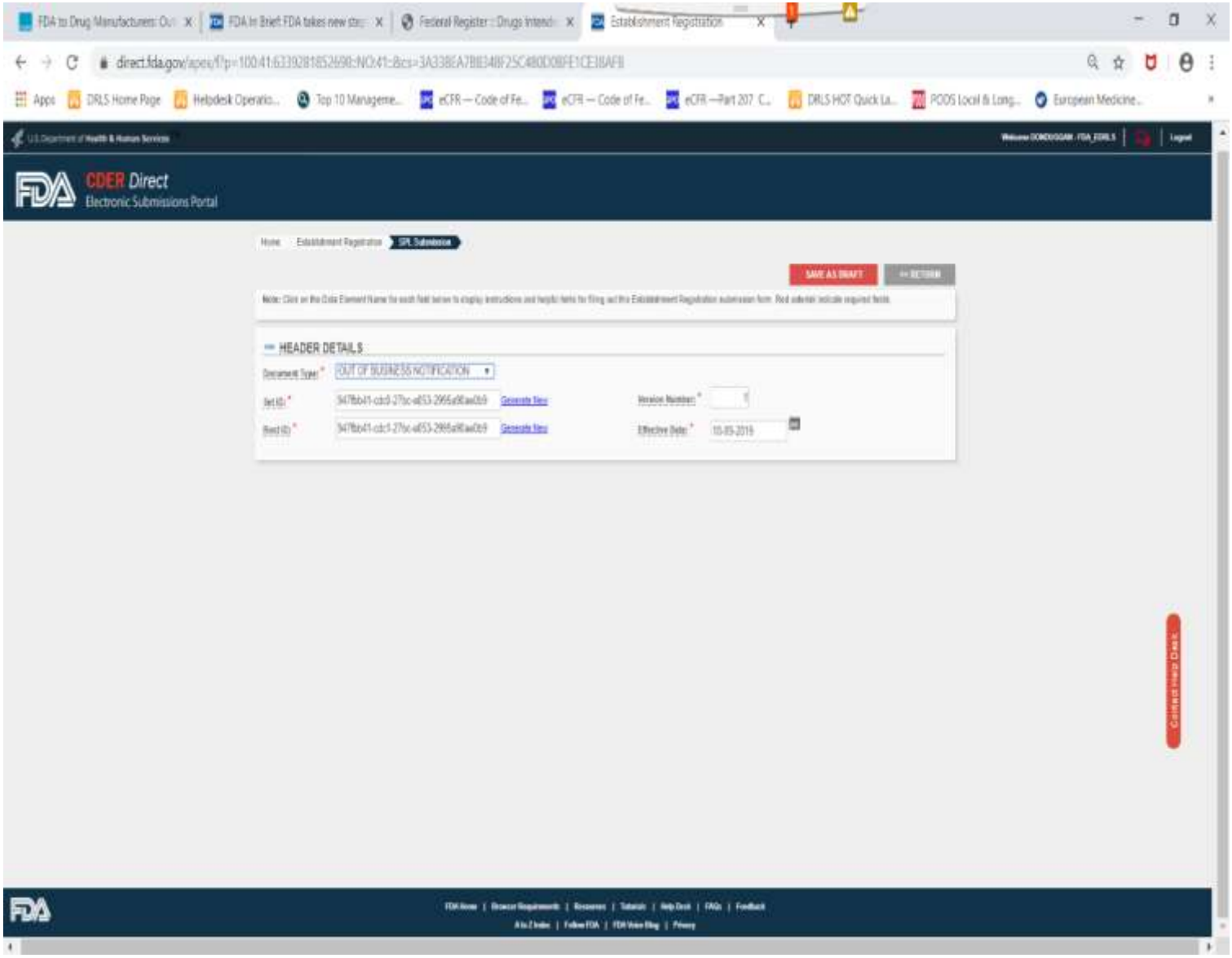
De-Registration SPL



Out of Business SPL

- Firm is no longer in business

Out of Business SPL



Tips for Establishment Registration

- Ensure that the Establishment information you enter (company name and address) exactly matches what is in the DUNS record.
- Ensure that all email addresses are valid and accurate as future FDA correspondence will be sent to the email contact addresses provided.
- Multiple Establishments can be registered using one Establishment Registration SPL.
- If your Establishment Registration SPL is grayed out and you are unable to edit a field, click on “Create New Version” to edit the SPL.

A Quick Word - Mergers and Acquisitions

- A change in a legal entity name or merger requires the listing firm to update the information with FDA. This update includes revising of the Labeler Code Request SPL, Registration SPL (if any) and all drug Listing SPLs under that labeler code to reflect the new name.

Avoid Errors with Registration

- Use the ***Same*** SET ID, a ***Different*** Root ID, and one higher version number when updating a SPL.
- After the Business Operations Don't forget the Qualifier! Ex. Human OTC, Animal RX, etc…
- Phone format is often not correct. Use a hyphen, you can click on the "Format" to see an example.
- Save and Validate your Establishment Registration SPL before sending.
- You must click the "Submit SPL" button to send the SPL to the FDA.

If you do receive an error

- Read the error messages. They will often direct you to the problem. You can then look in the manual for help.
- If you use CDERDirect
- Provide screenshots of the error message and the data causing the error
  - Send the screenshots to edrls@fda.hhs.gov with an explanation of what you are trying to do
  - For submissions created with Pragmatic sent through the Electronic Submissions Gateway (ESG) using Webtrader or Axway please contact the SPL Coordinator spl@fda.hhs.gov

The Drug Establishments Current Registration Site (DECRS)

- DECRS is a publication of currently registered establishments (facilities) which manufacture, prepare, propagate, compound or process drugs that are commercially distributed in the U.S. or offered for import to the U.S.
- **Download and Search available**
- Drug Firm Registration Search
- Drug Establishment Annual Registration Status Download File (ZIP)
  Last updated:10/8/2019

DECRS Contd.

- This database does not contain establishments registered as Human Drug Compounding Outsourcing Facilities under 503B. For a list of current 503B registrants, see: Outsourcing Facilities. An outsourcing facility may also appear in the DECRS database if it also registered under other business operations.
- This database does not contain prescription drug wholesale distributors and third-party logistics providers (3PLs) that report licensure annually to the FDA as required by the Drug Supply Chain Security Act.. See: Wholesale Distributor and Third Party Logistics Providers Reporting For more information.

Challenge Questions

- Should Private Label Distributors register before listing their products?
- Will a Product Listing SPL fail validation if the Establishment is not registered?
- Regarding Establishment Registration the rule is only one Establishment per SPL .

- For questions on the electronic registration and listing requirements send an inquiry to eDRLS@fda.hhs.gov

  If you have used Pragmatic and submitted your electronic registration through the ESG and have questions on the status of your submission, please contact the SPL Coordinator at SPL@fda.hhs.gov

  Electronic Drug Registration and Listing Instruction

  Points of Contact for Drug Registration andListing

U.S. FOOD & DRUG ADMINISTRATION

Thank you, Thank you very much